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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David B. Masters

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EXAMINER

SULLIVAN, DANIELLE D

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/922,418	Applicant(s) MASTERS, DAVID B.	
	Examiner DANIELLE SULLIVAN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-98, 133, 134 and 136-168 is/are pending in the application.
- 4a) Of the above claim(s) 4, 8-10, 18-49, 53, 57-59, 67-98, 133, 134 and 136-168 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 11-17, 50-52, 54-56 and 60-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/21/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-98, 133, 134 and 136-168 are pending. Claims 1-3, 5-7, 11-17, 50-52, 54-56 and 60-66 are currently under examination. Claims 4, 8-10, 18-49, 53, 57-59, 67-98, 133, 134 and 136-168 are withdrawn as being drawn to non-elected invention.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-17 and 50-66 in the reply filed on 8/05/2008 is acknowledged. The traversal is on the ground(s) that the restriction requirement has no serious burden and a search for the subject matter of any one group would encompass a search for all groups. This is not found persuasive because the device can be made from a materially different method which does not require the step of forming a film such as a method of molding a stent. Additionally, the device of Group I is materially different from the protein matrix because conductive materials are excluded from the device.

The requirement is still deemed proper and is therefore made FINAL.

Withdrawn rejections

Applicant's amendments and arguments filed 8/05/2008 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim does not end with a period and is therefore indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 11-17, 50-52, 54-56 and 60-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dinh et al. (US 5,510,077) in view of Greenbach (4,405,311).

Applicant's Invention

Applicant claims a drug delivery device comprising one or more polymers, conductive materials, pharmacologically active agents and solvents which form a cohesive body. The proteins may be selected from fibrinogen and thrombin. The solvents may be selected from water, DMSO, alcohols, acids, oils or glycols which are biocompatible. The polymer is selected from silicones, polyurethane and polylactic

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acid. The conductive materials are selected from gold, silver, aluminum and copper. A crosslinking agent selected from glutaraldehyde maybe added.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Dinh et al. teaches a stent comprising fibrin that is molded by compression for implantation in a human (abstract; column 3, lines 1-3). The fibrin is generated by crosslinking action of thrombin on fibrinogen (column 3, lines 59-67). The shape is provided by molding. The stent is made of a porous polymeric sheet into which fibrin is incorporated by applying by a solvent water (column 5, lines 34-64). Drugs may be incorporated into the stent and include anticoagulants, anti-inflammatory agents (column 6, lines 4-13). Glutaraldehyde may be added to increase stability as a fixing agent (crosslinking agent) (column 4, lines 54-56).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Dinh et al. does not teach a conductive material. It is for this reason that Greenbach is joined.

Greenbach teaches a method for treating arthritis by injection of electrically charged gold ions by a source of a direct current (abstract). The gold alloy may additionally contain palladium, platinum and zinc (column 3, lines 5-13). The apparatus is housed in a reaction-free material that is implantable in the body of a human (column 2, lines 26-29). Gold is administered as an alloy for the treatment of arthritis (column 1, lines 7-10).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Dinh et al. and Greenbach to further include a conductive material, specifically gold alloy. One would have been motivated to include gold alloy because Greenbach teaches that gold is a pharmacologically active ingredient used for the treatment of arthritis. Therefore, one would have been motivated to use gold as a conductive material in the drug delivery device taught by Dinh et al. because Greenbach teaches that gold can be housed in a reaction free material implantable into a human.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Urist (US 4,596,574) and Folkman et al. (US 5,019,372) teach protein delivery systems which contain ceramic or colloidal materials, respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
Art Unit 1616

/Johann R. Richter/
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